



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FEB 22 2007

Re: Isolex 300 and 300i
Dockets Nos. 1999E-5115
1999E-5118
2006E-0488
2006E-0489

The Honorable Jon Dudas
Undersecretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Dudas:

This is in regard to the applications for patent term extension filed by The Johns Hopkins University under 35 U.S.C. § 156 for U.S. Patent Numbers: 4,714,680; 4,965,204; 5,035,994; and 5,130,144. The medical devices claimed by the patents are Isolex 300 and 300i Magnetic Cell Selection System, and were assigned PMA No. 97-0001.

A review of the Food and Drug Administration's official records indicates that this product was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. § 156(a)(4). Our records also indicate that it represents the first permitted commercial marketing or use of the product, as defined under 35 U.S.C. § 156(f)(1).

The PMA was approved on July 2, 1999, which makes the submission of the patent term extension applications on August 31, 1999, timely within the meaning of 35 U.S.C. § 156(d)(1).

Should you conclude that the subject patents are eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C. § 156(d)(2)(A) we will then determine the applicable regulatory review period, publish the determination in the *Federal Register*, and notify you of our determination.

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

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